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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,910	12/28/2001	Hiroshi Nagasawa	NAGASAWA=6	2855

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 02/24/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,910

Applicant(s)

NAGASAWA, HIROSHI

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

FINAL ACTION

1. This action is in response to papers filed 13 December 2002 in Paper No. 6 in which claims 1-5 were canceled and claims 6-11 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 5 dated 24 June 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejection and new grounds for rejection. New grounds for rejection are discussed.

Claims 6-11 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 8 is indefinite in step "b", line 1 for the recitation "a plurality of different capillaries" because it is unclear whether the capillaries are those prepared in step "a". Step "b" is further indefinite because it is unclear whether "the capillaries", "said capillaries" and "each capillary" refer to the capillaries of step "a" or step "b". It is suggested that Claim 8 be

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amended to clarify e.g. in step “a” before “capillaries” insert, “a plurality of different” or in step “b” replace “a plurality of different” with “said”.

b. Claim 9 is indefinite in line 7, for the recitation “binding analyte from the sample” because the recitation lacks proper antecedent basis in the sample of line 2. It is suggested that Claim 9 be amended to provide proper antecedent basis e.g. in line 1, after “sample”, insert “comprising an analyte”.

c. Claim 9 is indefinite in step “b” for the recitation “the capillary bundle” because the recitation lacks proper antecedent basis in the “bundle of capillaries” of step “a”. It is suggested that Claim 9 be amended to provide proper antecedent basis e.g. replace “capillary bundle” with “bundle of capillaries”.

d. Claim 10 is indefinite in “b” because it is unclear whether the “binding substance” is the probe molecules fixed to an inner surface of the capillaries of Claim 6 or whether the substance is another and different substance. It is suggested that Claim 10 be amended to clarify.

e. Claim 10 is indefinite in “c” for the recitation “the analyte-bound chip” because the recitation lacks proper antecedent basis in “b” which does not describe an analyte-bound chip.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 6-9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al (U.S. Patent Application Publication No. 2002/0055111 A1, filed 25 August 2000).

Regarding Claim 6, Chen et al disclose an affinity analytical chip comprising a plurality of capillaries bundled together each of said capillaries having a diameter of greater than about 10 microns and a length of about 1 to 5 m m and having fixed to an inner surface thereof, a probe molecules having a specific affinity to an analyte (§ 16-20 and 58).

Regarding Claim 7, Chen et al disclose the affinity chip of Claim 6 wherein the probe molecule is selected from the group consisting of DNA, RNA, DNA fragments, RNA fragments, oligonucleotides, antigens, antibodies, epitopes, and proteins (§ 46 and 48).

Regarding Claim 8, Chen et al disclose a method for producing an affinity analytical chip comprising preparing capillaries each of which has a probe molecule fixed to the inner surface thereof and bundling a plurality of different capillaries together while precisely positioning the capillaries into a bundle wherein each capillary in the bundle has a different probe molecule (§ 56 and 73-83).

Regarding Claim 9, Chen et al disclose an analytical method comprising flowing a sample into a bundle of capillaries having fixed to the inner surface of the capillaries probe molecules having a specific affinity to an analyte to be detected to cause specific binding reactions between the probe molecules and the analyte thereby binding analyte from the sample to the inner surface of the capillaries, introducing light into one end of the capillary

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bundle and detecting light exiting from an opposite end of the capillary bundle (§ 85, 88, 97 and 98).

Regarding Claim 11, Chen et al disclose the chip of Claim 6 wherein the probe has a specific affinity different from that of a probe fixed to another capillary (§ 20).

6. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Dehlinger (sup 5,763,263, issued 9 June 1998).

Regarding Claim 9, Dehlinger discloses a detection method comprising flowing a sample into a bundle of capillaries having fixed to an inner surface thereof probe molecules having different specific affinity to an analyte to be detected to cause specific binding, thereby binding analyte from the sample to the inner surface of the capillaries; introducing light from one end of the capillary bundle; and detecting light exiting from an opposite en of the capillary bundle (Column 18, lines 5-45 and Fig. 11A and 11B).

7. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Landegren et al (WO 96/17246, published 6 June 1996).

Regarding Claim 8, Landegren et al disclose a method or producing an affinity analytical chip comprising preparing capillaries each of which has a probe molecule fixed to the inner surface thereof and bundling a plurality of different capillaries into a bundle of said capillaries wherein each capillary in the bundle has a different probe molecule (page 1, first paragraph, page 2, lines 15-37 and Claim 11).

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Respons to Arguments

8. Applicant argues that Dehlinger and Landgren do not teach the instantly claimed arrays wherein the capillaries have a length of from about 1 to 5 m m. The argument has been considered but is not found persuasive regarding the inventions of Claims 8 and 9 because the methods of Claim 8 and 9 are not limited to capillaries having a length of from about 1 to 5 m m. However, if the methods of Claims 8 and 9 were amended to include the length limitation, the methods would be obvious in view of the prior art. As discussed below, Schellenberger teaches capillary lengths of from about 1 to 5 m m. Therefore, methods limited to the recited capillary lengths would be obvious in view of Schellenberger.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 6, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263, issued 9 June 1998) in view of Schellenberger et al (U.S. Patent No. 6,306,578 B1, filed 17 March 2000).

Regarding Claim 6, Dehlinger teaches an affinity analytical chip comprising a plurality of capillaries bundled together said capillaries having fixed to an inner surface thereof a probe molecule having different specific binding reactivity wherein the capillaries have a diameter greater than 10 microns and typically a length of 1cm (Column 3, lines 54-64 and Column 8, lines 17-33) but they do not teach a length of about 1 to 5 m m. However, analytical chips

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comprising bundled capillaries having a length of about 1 to 5 m m were known in the art at the time the claimed invention was made as taught by Schellenberger et al who teach the preferred length is between 1m m and 1 cm (Column 8, line 63-Column 9, line 10) which encompasses the instantly claimed range of 1 to 5 m m. Dehlinger teaches a capillary length of 1cm, Schellenberger et al teaches the similar chip wherein the preferred length is less than 1 cm i.e. between 1m m and 1 cm (Column 8, line 63-Column 9, line 10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the capillary length of Dehlinger with the instantly claimed 1-5 m m capillary based on the preferred shorter capillaries as taught by Schellenberger et al (Column 8, line 63-Column 9, line 10) to thereby optimize the Dehlinger chip utilizing a preferred shorter capillary.

Schellenberger et al teaches the preferred capillary length is between 1m m and 1 cm (Column 8, line 63-Column 9, line 10) which overlaps the instantly claimed range of 1 to 5 m m. Because the instantly claimed range lies within the range of Schellenberger et al, one of ordinary skill in the art would have expected the instantly claimed range to have properties similar to those of Schellenberger et al. Absent evidence demonstrating that the instantly claimed range is critical to the invention or provides unexpected results, the instantly claimed range of capillary length would have been obvious in view of the teaching of Dehlinger and Schellenberger et al.

When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims.

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The courts have stated where the claimed ranges “overlap or lie inside the ranges disclose by the prior art” and even when the claimed ranges and prior art ranges do not overlap but are closed enough that one skilled in the art would have expected them to have similar properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (see MPEP, 2144.05 I.). Therefore, the claimed ranges

Regarding Claim 7, Dehlinger teaches the chip wherein the probe molecules are DNAs, RNAs, oligonucleotides, proteins, peptides, antigen, epitope (Column 6, lines 51-59).

Regarding Claim 10, Dehlinger discloses an apparatus for analyzing affinity of a material comprising an analytical affinity chip, a binding substance for binding an analyte to the chip i.e. probe molecules (Column 6, lines 51-59) a light absorption observation device comprising a housing for holding the analyte-bound chip, a light emitting portion provided ahead of the housing and an observation unit provided behind the housing; and a data processing device connected to the light absorption observation device i.e. photodiode array, photodiode detector elements and position detection via optical input from each photodiode (Column 18, lines 29-39 and Fig 11 B) wherein the affinity chip comprises a plurality of capillaries bundled together said capillaries having fixed to an inner surface thereof a probe molecule having different specific binding reactivity wherein the capillaries have a diameter greater than 10 microns and typically a length of 1cm (Column 3, lines 54-64 and Column 8, lines 17-33) but they do not teach a length of about 1 to 5 m m. However, analytical chips comprising bundled capillaries having a length of about 1 to 5 m m were known in the art at the time the claimed invention was made as taught by Schellenberger et al who teach the preferred length is between 1m m and 1 cm (Column 8, line 63-Column 9, line 10) which encompasses the instantly claimed range of 1 to 5 m m. Dehlinger teaches a capillary length of 1cm, Schellenberger et al teaches the similar chip wherein the preferred length is less than

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1 cm i.e. between 1m m and 1 cm (Column 8, line 63-Column 9, line 10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the capillary length of Dehlinger with the instantly claimed 1-5 m m capillary based on the preferred shorter capillaries as taught by Schellenberger et al (Column 8, line 63-Column 9, line 10) to thereby optimize the Dehlinger chip utilizing a preferred shorter capillary.

Schellenberger et al teaches the preferred capillary length is between 1m m and 1 cm (Column 8, line 63-Column 9, line 10) which overlaps the instantly claimed range of 1 to 5 m m. Because the instantly claimed range lies within the range of Schellenberger et al, one of ordinary skill in the art would have expected the instantly claimed range to have properties similar to those of Schellenberger et al. Absent evidence demonstrating that the instantly claimed range is critical to the invention or provides unexpected results, the instantly claimed range of capillary length would have been obvious in view of the teaching of Dehlinger and Schellenberger et al.

Regarding Claim 11, Dehlinger teaches the chip wherein the probe has a specific affinity different from that of a probe fixed to another capillary (Column 4, line 65-Column 5, line 4).

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (U.S. Patent No. 5,763,263, issued 9 June 1998) in view of Landegren et al (WO 96/17246, published 6 June 1996).

Regarding Claim 8, Dehlinger teaches a method for producing an affinity analytical chip comprising preparing a plurality of capillaries each of which has a probe molecule fixed to the inner surface thereof and bundling a plurality of capillaries together precisely wherein each

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capillary in the bundle has a different probe molecule (Column 3, lines 54-64; Column 4, line 65-Column 5, line 4; and Column 8, lines 17-33) but they do not teach the prepared capillaries have probe affixed prior to capillary bundling. However, Landegren et al teach a similar method comprising preparing capillaries each of which has a probe molecule fixed to the inner surface thereof and bundling a plurality of different capillaries into a bundle of said capillaries wherein each capillary in the bundle has a different probe molecule (page 1, first paragraph, page 2, lines 15-37 and Claim 11) wherein capillary preparation prior to bundling permits verification that the molecule fixed within the capillaries are correct prior to chip creation (page 3, 31-page 4, line 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify apply the capillary preparation prior to bundling as taught by Landegren et al to the Dehlinger chip production to thereby determine correctness of affixed probes for the expected benefit of controlling the quality of the chip produced as taught by Landegren et al (page 3, 31-page 4, line 1).

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
February 13, 2003